November 30, 1999

Document Management Branch
(HFA-305)
Food & Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

To Whom It May Concern:

My name is David A. Cavanaugh, M.D. I am a neurosurgeon in Shreveport, . Louisiana, in active private practice. I am writing in regards to the proposed FDA regulations that could possibly allow regulations of some types of allograft and medical devices. This letter is in reference to Docket #97N-484S for your records.

As I mentioned above, in active neurosurgical practice, I use approximately 30-40 bone bank grafts per year in anterior cervical discectomy with fusion. I am writing today to express my concerns regarding the possible FDA regulation, such as sponsoring clinical trials and lengthy regulatory documents in relation to the use of bone bank grafts. I feel that bone banks do not have the resources or the expertise to satisfy the FDA's requirements, and this will put undue stress and time constraints on patients needing these products.

It is my recommendation that this regulation be revisited and inhibited from progression. Please address my concerns as public comments regarding this issue. If I may be of any assistance in this matter, please do not hesitate to contact me at th address and number above. Thank you for your time and consideration in this matter.

David A. Cavanaugh, M.D.

DAC/ph

97N-4845

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**GEORGE D. BEACH, M.D.**
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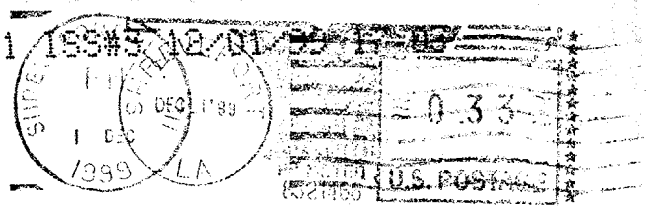
SHREVEPORT LA 711 ISS#5 12/01 [illegible]

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